# **EXHIBITS 1-7** REDACTED IN THEIR **ENTIRETY**

## **EXHIBIT 8**

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S and ANTON MAYR

Plaintiffs,

v.

ACAMBIS INC. and ACAMBIS PLC,

Defendants.

Civil Action No. 05-614 (SLR)

### EXPERT REPORT OF DAVID EINHORN

### Introduction

I have been retained by Bavarian Nordic A/S( "Bavarian") in connection with this litigation pending before the U.S. District Court of Delaware to study and provide my opinion on certain issues relating to the customs of sharing, ownership and licensing of biological materials within the biomedical research community. In this litigation I understand that Bavarian claims that its proprietary technology in modified vaccinia Ankara("MVA") is being used without Bavarian's permission and for commercial purposes by Acambis Plc ("Acambis").

I hold a Bachelor of Science in Economics degree from the Wharton School of Finance and Commerce of the University of Pennsylvania, have studied at the London School of Economics and Political Science, and have a law degree from Georgetown University. I have practiced law in the States of New Jersey, New York and Maine and am currently employed as House Counsel of The Jackson Laboratory, 600 Main Street, Bar Harbor, Maine 04609. Over the past 16 years at The Jackson Laboratory, I have been involved in drafting, negotiating, approving and executing scores of legal documents involving the exchange, licensing and distribution of biological materials to and between academic, nonprofit, governmental, and forprofit entities. I am familiar in this context with material transfer agreements, license agreements, confidentiality agreements, collaborative research agreements, consulting agreements, etc., both with respect to patented and unpatented biological materials, and have negotiated such agreements with well more than 100 research institutions, both public and private, nonprofit and forprofit. I have also been involved in the provision of biological materials among scientists, including scientists at the National Institutes of Health("NIH"), that have not been accompanied by formal written agreements. I have been a speaker at conferences on technology transfer held by the Association of University Technology Managers, have lectured in Germany and Japan on technology transfer issues, and have worked with the National Institutes of Health on technology transfer issues of public concern. Additional information on my background is set forth in my curriculum vitae, which is annexed to this Report.

I am being compensated at a rate of \$350 per hour in this matter. I have never testified as an expert witness at a trial. I was deposed in concurrent litigation between these parties before the International Trade Commission.

In forming the opinions expressed below, I have reviewed documents provided by counsel for Bavarian, including those relating to the transfer of the MVA from Professor Anton Mayr to Therion Biologics and to Dr. Bernard Moss of the National Institute of Allergy and Infectious Diseases("NIAID") and from NIAID to Acambis, as well as other documents addressing the issues in this matter, including those listed in Exhibit A.

I have not yet selected or prepared any trial exhibits to supplement my testimony or to illustrate my opinions.

### **Expected Testimony and Opinions**

- 1. I am prepared to testify that when biological materials are shared or exchanged for "research purposes", "for research purposes only", or language of a similar nature, it is commonly understood in the academic, nonprofit, governmental and forprofit communities that the biological materials can only be used by the recipient of the materials for research and not for any "commercial purposes". It is further commonly understood that "commercial purposes" as distinguished from "research purposes", means sale of the biological materials or using the materials to manufacture something else for sale.
- 2. I am further prepared to testify that the sharing of biological materials among scientists is at the heart of the research commonly ethos that sharing will facilitate the advance of scientific knowledge in the public interest; and although the shared biological materials are often not accompanied by formal written agreements, that it is customarily understood that such shared materials are to be used by the recipient for research and not for commercial purposes. In this context, I believe that both Professor Mayr and Dr. Moss, as fellow academic and governmental researchers, understood that biological materials shared between them would be used for research and not for commercial purposes.
- 3. I may testify with respect to customs in the biomedical research community with respect to the transfer of research tools and NIH policies on sharing research tools.
- 4. I am further prepared to testify that it is commonly understood in the academic, nonprofit, governmental and forprofit communities that when the parties intend to have a formal legal document accompany the sharing of biological materials, the usual form is a material

transfer agreement. A material transfer agreement usually provides a recitation that ownership of the materials is claimed by the provider; that usually there is no consideration expected by the provider from the recipient other than the cost of the materials and/or shipping costs; that there is no transfer of intellectual property rights in the materials from the provider to the recipient; and that the recipient is only allowed to use the materials for its own research purposes. In distinction from a material transfer agreement, a license agreement normally provides for financial or other valuable consideration paid by the recipient to the provider for a grant of rights to use the materials for commercial purposes.

- 5. I have reviewed the document entitled, "Material Transfer Agreement" executed by NIAID and Acambis, wherein NIAID agreed to provide MVA to Acambis, and I am prepared to testify that this Material Transfer Agreement is unusual since it does not recite proprietary or ownership rights by NIAID in the MVA and purports to grant rights to use the MVA for commercial purposes. The grant of a commercial license in the Material Transfer Agreement is also I believe inconsistent with the non-commercial sharing of MVA material between two research scientists.
- 6. I may also testify from review of relevant documents and my understanding of customary practices typical of dealings between academics and companies, with respect to the following transactions:
  - a. Bavarian's acquisition of commercial rights to MVA from Professor Mayr through written agreements as the customary way by which companies obtain proprietary rights to biological materials.
  - b. Therion Biologics Corporation("Therion") efforts to obtain MVA from Professor Mayr and his insistence on restricting Therion's use for research purposes.
- 7. I am also prepared to testify that Professor Mayr's conduct in freely sharing MVA with Dr. Moss, and Professor Mayr's quite different response to the requests for MVA from commercial companies like Therion and Acambis, was typical of a basic research scientist who would assume based on the customs in the community that a researcher at the NIH would only

use MVA for research purposes, in contrast to a company like Therion which would be expected to be interested in MVA because of its commercial potential and from which Professor Mayr therefore took the precaution of requiring that MVA be used for research purposes only.

- I may also be asked to testify about transactions in this case involving MVA, 8. including agreements between Acambis, Therion and Baxter and Acambis and Baxter and transactions between Bavarian Nordic and other entities involving MVA.
- I may also be asked to testify about the RFP process, the RFP's relevant to this 9. case, the requirements for responses to those RFP's and the responses of Acambis and Bavarian Nordic to those RFPs.

I may supplement this Report if I become aware of additional pertinent information or in response to the restimony or reports of others.

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### **EXHIBIT A**

- The Material Transfer Agreement for the transfer of MVA from NIH to 1. Acambis.
- Documents between Acambis, Bavarian Nordic, Therion, NIH, Anton Mayr, and others regarding the transfers of the MVA strain at issue in this case.
- ITC Complaint and Exhibits attached to the original Complaint, including scientific data, secrecy and transfer agreements, RFPs 1 and 2, and Published articles regarding Acambis' and BN's strategic and financial positions; and the Answer.
- 4. Amended complaint and exhibits attached thereto, as filed in the Delaware case.
- 5. U.S. Patent Nos. 6,913,752 and 6,761,893
- 6. Bavarian Nordic Confidentiality Agreements with NIH and Acambis.
- 7. Higgins Memo reflecting IP position on Therion MVA, Bates number TBC00592 et seq.
- 8. German Opinion to Therion re MVA IP rights, Bates number TBC00013 et seq.
- 9. Correspondence between Acambis, Bavarian Nordic, Therion, NIH, Anton Mayr, and others regarding the transfer of the MVA strain.
- 10. November 6, 2002 letter from Anton Mayr to Bernard Moss requesting details of his activities with MVA obtained from Mayr.
- 11. November 6,1997 letter from Geoffrey Smith to Anton Mayr requesting permission to transfer MVA samples to Professor Dave Rowlands of the University of Leeds.
- August 4, 1997 letter from Tom Blanchard to Anton Mayr requesting permission to transfer MVA samples to Professor Warwick Britton.
- 13. September 26, 1995 Declaration of Value regarding transfer of MVA strain from Anton Mayr to Therion Biologics Corp.
- 14. 1995 correspondence between Bernard Moss and Anton Mayr regarding request for MVA-575 strain.
- 15. 2002 correspondence between Therion Biologics Corp. and Anton Mayr regarding request for MVA-572 strain.
- 16. March 30, 1998 consulting agreement between Bernard Moss and with OraVax, Inc.
- 17. The Non-Confidential version of Acambis' Response to the ITC complaint.
- Acambis' Response to Bavarian Nordic's Amended Delaware Complaint. 18.

- 19. November 26, 1997 correspondence between Peter Wulff and Bernard Moss regarding patent no. WO 97/02355.
- 20. September 21, 2001 letter from Anton Mayr to Bernard Moss describing MVA-572 strain sent from Mayr to Moss.
- 21. June 30, 2003 letter from Peter Wulff to Anton Mayr attaching new consultancy agreement.
- 22. July 4, 2003 letter from Anton Mayr to Peter Wulff regarding consultancy agreement and Mayr's research.
- 23. November 1997 email correspondence between Peter Wulff and Geoffrey Smith regarding transfer of MVA strain.
- 24. February 2000 correspondence between Paul Howley and Anton Mayr regarding development of MVA strain.
- 25. June 2002 facsimile of statement from Anton Mayr that he provided Bavarian Nordic with the Elstree Vaccinia strain.
- 26. 2002-2003 correspondence between Bavarian Nordic, the NIH, Bernard Moss, Acambis, and Anton Mayr regarding rights to use MVA.
- 27. August 21, 2002, email from Thomas Monath to various Acambis employees relating a conversation between Monath and Bernard Moss re: Acambis' intention to use an MVA strain obtained from Therion Biologics Corp.
- 28. April 14, 2002 letter from Acambis to NIAID attaching confidential disclosure agreement.
- 29. January 17, 2003 letter from Roger McAvoy to Jacqueline Holden of NIH regarding Acambis' failure to conduct an analysis of third-party intellectual property rights in MVA.
- 30. January 17, 2003 letter from Michael Mowatt to Roger McAvoy urging Acambis to conduct an analysis of third-party intellectual property rights in MVA
- 31. November 27, 2002 cover letter and Materials Transfer Agreement between the NIH and Acambis.
- 32. February 26, 2002 Secrecy Agreement between Bavarian Nordic and Acambis.
- 33. December 10, 2002 letter (redacted) from Therion to Acambis regarding Therion's asserted intellectual property position regarding MVA.
- The Confidential version of Acambis' Response to the ITC complaint.
- 35. Acambis' Answer to Bavarian Nordic's Amended Complaint filed in the Delaware case.

- 36. Anton Mayr's Confidential declaration included as an exhibit to Bavarian Nordic's Opposition to Acambis' Motion to Terminate, regarding Mayr's transfer of MVA strains.
- 37. Correspondence between Therion Biologics Corp. and Acambis regarding termination of their agreement to use an MVA strain supplied by Therion.
- Deposition Transcript of Nick Higgins (August 26, 2006) and exhibits.
- 39. Deposition Transcript of Roger McAvoy (September 15, 2006) and exhibits.
- 40. Deposition Transcript of Bernard Moss (August 28, 2006) and exhibits.
- 41. Deposition Transcript of Anton Mayr (September 21, 2006) and exhibits.
- 42. Deposition Transcript of Anton Mayr (December 14, 2005) and exhibits.
- Bavarian Nordic and Oxxon License. 43.
- Bavarian Nordic and Transgene License. 44.
- 45. "Journal of General Virology Instructions for Authors," HTML version last modified 25 August 2006, printed from http://vir.sgmjournals.org/misc/ifora.shtml, with instructions for online submissions of papers for publication.
- 46. "JCB -- Instructions to Authors," printed from http://www.jcb.org/misc/ifora.shtml, with instructions for submission of manuscripts.
- 47. Journal of Virology, Jan. 2006, p. 1-17, article entitled "2006 Instructions to Authors."
- 48. Expert Report of Prof. Joseph Straus.
- 49. Anton Mayr-Bavarian Nordic Agreement 1 June 1996.
- 50. Anton Mayr-Bayarian Nordic Agreement 1 June 1999.
- 51. Anton Mayr-Bavarian Nordic Agreement 1 June 2001.
- 52. Anton Mayr-Bayarian Nordic Agreement 1 June 2003.
- 53. Anton Mayr-Bavarian Nordic Agreement 6 Nov 2002.
- 54. Anton Mayr-Bavarian Nordic Agreement 19 Apr 2004.
- 55. Anton Mayr-Bavarian Nordic Agreement 24 Mar 2004.
- 56. Anton Mayr-POA and Rights. (BNDEL001269).
- 57. August 3, 2001 Dr. Moss Letter to Anton Mayr. (BNDEL001259).

- 58. September 12, 2001 Anton Mayr Letter to Dr. Moss.
- 59. September 14, 1995 Dr. Moss Letter to Anton Mayr.
- 60. September 19, 1995 Anton Mayr Letter to Dr. Moss.
- 61. Article by H. Stickl, V. Hochstein-Mintzel, A. Mayr, H. Ch. Huber, H. Schäfer and A. Holzner, entitled "MVA Vaccination Against Smallpox; Clinical Tests with an Attenuated Live Vaccinia Virus Strain (MVA)," Dtsch. med. Wschr. 99 (1974), 2386-2392.
- 62. Article by H. Stickl and V. Hochstein-Mintzel, entitled "Intracutaneous Smallpox Vaccination with a Vaccinia Virus Having Attenuated Virulence ("MVA virus")," <u>Social Medicine and Hygiene</u>, from the Bavarian State Vaccination Institute, Munich (Director: Prof. H. Stickl, M.D.).
- 63. DBM0001-0097.

### **CURRICULUM VITAE** DAVID EINHORN, ESO.

**PERSONAL** 

Address:

26 Atlantic Avenue

Bar Harbor, Maine 04609

Telephone: Date of Birth:

(207) 288-9791 October 31, 1940

Marital Status:

Married to Marilyn Baum

Children: Jesse Aaron

**EDUCATION** 

Passaic High School, Passaic, New Jersey

Wharton School of Finance and Commerce University of Pennsylvania (B.S.E.)

(1962)

London School of Economics and Political Science, University of London (1960-1961)

Georgetown Law School

Georgetown University (L.L.B.) (1965)

**EMPLOYMENT** 

Civil Rights Clerkship Smith, Waltzer, Jones and Peebles, Esqs. New Orleans, Louisiana (1964)

Associate of Sellinger and Chester, Esqs.

Passaic, New Jersey (1965-1967)

Private general practice at 21 East 40th Street, New York City, and 307 Monroe Street, Passaic, New Jersey, (1968-1969)

Executive Director of Union County Legal Services Corporation (1969-1974)

Special Assistant for Legal Affairs State of New Jersey Department of Institutions and Agencies (1974-1976)

Deputy Commissioner, State of New Jersey Department of Human

Services (1976-1979)

Consultant to Daniel and Florence Guggenheim Foundation Project on Criminal Justice at Princeton University and Yale Law School (1981)

Private general practice in Milford, New Jersey (1982-1985)

Consultant to the Legal Services Corporation, Washington, D.C. (1985)

Of Counsel with Fenton, Chapman, Fenton, Smith and Kane, Esqs. Bar Harbor, Maine (1986-1994)

House Counsel, The Jackson Laboratory, Bar Harbor, Maine

(1989-Present)

BAR ADMISSIONS

Admitted to the New Jersey Bar (1965)(inactive) Admitted to the New York Bar (1968)(inactive)

Admitted to the Maine Bar (1986)

**ASSOCIATIONS** 

Past Member of the Union County, Passaic County and

**Hunterdon County Bar Associations** 

Past lecturer of the New Jersey Institute for Continuing Legal

**Education Skills Training Course** 

Past Member of the New Jersey Public Employment Relations

Commission Panel of Grievance Arbitrators

Past Arbitrator of the American Arbitration Association

**BOARDS** 

Past Chairman, Town of Bar Harbor Planning Board

Past Chairman, State Advisory Council to the New Jersey

Department of Corrections

Past Member, Board of Peter W. Rodino Institute for

Criminal Justice

Past Member, Mental Health Association of Hunterdon

County, New Jersey

**TEACHING** 

Criminal Justice Program Woodrow Wilson School of Public and

International Affairs, Princeton University (1976)

Adjunct Faculty, College of the Atlantic, Bar Harbor Maine

**PUBLICATIONS** 

"Sharing Research Tools: The Laboratory Mouse"
Sundberg JP, Ichiki T (eds.), Handbook on Genetically
Engineered Mice, CRC Press, Boca Raton, Fl. (in press)

## **EXHIBIT 9**

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIO	C A/S,	
	Plaintiff,	)
v.	·	) Civil Action No. 05-614
ACAMBIS INC. and ACAMBIS, PLC,		)
	Defendants.	) ) )

### **EXPERT REPORT OF ROBERT DRILLIEN**

### I. INTRODUCTION

- 1. My name is Robert Drillien and I hold a position at the Institute of Genetics and Molecular and Cellular Biology ("IGBMC") in Strasbourg, France, which is one of the leading European Centers for biomedical research. My own research focuses on virology with emphasis on the analysis of vaccinia virus strains such as Modified Vaccinia Ankara ("MVA").
- 2. I have been retained as a scientific expert by Bavarian Nordic A/S ("BN") in connection with the above-referenced lawsuit to study and provide my opinion on certain issues relating to academic research and biopharmaceutical industry practices.
- 3. I understand that BN claims that a specific biological material referenced to as MVA-572 has been unlawfully converted by Acambis, which I understand is one of the allegations of unfair trade practices raised against Acambis in this case.

### II. QUALIFICATIONS

- 4. I hold a Bachelor of Science degree in Biochemistry, a Master in Biochemistry and a Ph.D. in Virology. I have essentially conducted scientific research in academia since 1970 and have specifically focused on the field of virology for the past 30 years. At the academic level I collaborate with researchers globally in the field of Poxviruses (the family of viruses that includes vaccinia virus and the smallpox virus known as variola) and I am a member of the World Health Organization ("WHO") Advisory Committee on Variola Virus Research, reviewing the progress of research involving live variola virus.
- 5. I am being compensated at a rate of \$200 per hour in this matter. I have previously testified as an expert and been deposed for trial in concurrent litigation between these parties before the International Trade Commission. I have also been retained as an expert in concurrent litigation between the parties at the Commercial Court of Vienna, Austria. Aside from these companion cases, I have never previously testified as an expert or been deposed for trial, nor been retained as or testified as an expert on this subject matter in any other litigation.
- 6. In forming the opinions expressed below, I have reviewed and relied on my knowledge encompassing more than 30 years of research in the field of Poxviruses, including the specific field of vaccinia virus and MVA, and certain documents listed in Exhibit A.
- 7. I have not selected or prepared any trial exhibits to supplement my testimony and illustrate my expressed opinions at this time.

### III. EXPECTED TESTIMONY AND OPINIONS

8. I am prepared to provide an overview of MVA technology at issue in this case and to testify about MVA strains and their history and qualities; the history of smallpox disease

and vaccines against smallpox; and vaccines against smallpox and other diseases based on the MVA virus. I am also prepared to testify about how organizations, such as the WHO, and nations respond to smallpox and other threats of disease and biological weapons.

- 9. I am prepared to testify on the conversion of the MVA-572 strain by Acambis for Acambis' commercial use, the significance of access to this particular MVA strain to achieve an expeditious development of an MVA vaccine product to pursue a Biologic License Application ("BLA") at the FDA. Use of this particular strain because of the year of its creation enables one to avoid certain regulatory hurdles and warning labels relating to bovine spongiform encephalopathy ("BSE") and/or transmissible spongiform encephalopathy ("TSE"). Thus, MVA-572 is an important and desirable MVA virus material.
- 10. I am prepared to testify about how access to MVA biological material, including the Therion MVA virus or MVA-572, grown up into a seed stock at NIH, was necessary for Acambis to bid on RFP 1, 2 and 3 and receive contracts to supply over 505,000 doses of MVA vaccines to the U.S. Government.
- 11. I am prepared to testify that Acambis made commercial use of the seed stock received from NIH for Acambis' smallpox vaccine product MVA3000, also sometimes called ACAM3000.
- 12. I am prepared to testify about research and industry practices regarding the provision of live biological material, such as MVA virus strains, among scientists associated, including scientists associated with research institutions. I am prepared to testify that in such circumstances, without an explicit agreement that the strain may be used for commercial purposes, the live biological material or strain cannot be used for commercial purposes.
  - 13. In particular, it is my opinion that the transfer of live biological material to a

research institution, absent a written agreement, takes place with the understanding that the biological material's use will be limited to research purposes only.

- Moreover, it is my opinion that it is industry practice for a research institution to 14. enter into an explicit, written agreement, when the exchange of biological material is intended for commercial purposes, such as the development of a commercial product.
- I may be called upon to testify about research and industry practices within the 15. scientific community in Europe and the U.S., regarding the provision of live biological material, such as MVA strains, to a research institution. In particular, it is my opinion that the transfer of live biological material to a research institution, absent a written agreement, takes place with the understanding that the biological material's use will be limited to research purposes only. Moreover, it is my opinion that it is industry practice for a research institution to enter into an explicit, written agreement, when the exchange of biological material is intended for commercial purposes, such as the development of a commercial product.

#### IV. MATERIALS CONSIDERED

- I have attached to this report a list of materials that I reviewed and considered in 16. forming the basis for my opinions.
- I reserve the right to continue to review materials that have been produced in this 17. case, and supplement my expected testimony based on the review of such additional materials. I further reserve the right to review the reports of other experts in this case, including any experts put forth by Acambis, and supplement my opinions based on any such reports.

Respectfully submitted, October 12, 2006

Robert Drillien 14 rue Waldteufel Strasbourg, France 

## **EXHIBIT A**

- 1. Bavarian Nordic's ITC Complaint (Inv. No. 337-TA-550) and Exhibits attached to the original Complaint; and the Confidential version of Acambis' Response to the ITC complaint.
- Bavarian Nordic's Delaware Amended Complaint (Civil Action No. 05-614 (SLR)) and Exhibits attached to the original Complaint; and Acambis' Response to the Delaware complaint.
- 3. U.S. Patent Nos. 6,913,752 and 6,761,893.
- Bavarian Nordic's interrogatories responses in the ITC case (Inv. No. 337-4. TA-550) and the Delaware case.
- Acambis' interrogatory responses in the ITC case (Inv. No. 337-TA-550) 5. and the Delaware case.
- 6. The 30(b)(6) Deposition transcript of Cynthia Lee (December 5, 2005) and exhibits in the ITC case (Inv. No. 337-TA-550).
- 7. The Deposition transcript of Dr. Robert Drillien March 8, 2006, and exhibits in the ITC case (Inv. No. 337-TA-550).
- The Deposition transcript of Dr. Robert Drillien March 9, 2006, and exhibits in the ITC case (Inv. No. 337-TA-550).
- 9. The Deposition transcript of Dr. Miles Carroll, and exhibits (March 1, 2006).
- 10. The Deposition transcript of Dr. Miles Carroll, and exhibits (March 2, 2006).
- The Deposition transcript of Dr. Miles Carroll, and exhibits (July 23, 2006).
- 12. The Expert Report of Dr. Milles Carroll, and exhibits in the ITC case (Inv. No. 337-TA-550).
- 13. The Expert Report of Dr. Robert Drillien, and exhibits in the ITC case (Inv. No. 337-TA-550) (RX-273C:1-13).
- 14. The Rebuttal to Expert Report of Dr. Milles Carroll and to the Technical Aspects of the Expert Report of Michael Sofocleous, and exhibits in the ITC case (Inv. No. 337-TA-550).
- 15. The Rebuttal to Expert Report of Dr. Robert Drillien, and exhibits in the ITC case (Inv. No. 337-TA-550).
- 16. The Expert Report of Dr. Leonard Schultz, and exhibits in the ITC case (Inv. No. 337-TA-550).
- 17. Dr. Robert Drillien's Witness Statement from the ITC case (Inv. No. 337-TA-550) (CX-243C-1-122).

- 18. Dr. Miles Carroll's Witness Statement from the ITC case (Inv. No. 337-TA-550) (RX-649C:1-153; RX-650C:1-121).
- 19. The trial hearing testimony of Dr. Milles Carroll from the ITC case (Inv. No. 337-TA-550).
- 20. The trial hearing testimony of Dr. Robert Drillien from the ITC case (Inv. No. 337-TA-550).
- 21. VIVACS # 1200104 (aka Vivacs 1) from the ITC case (Inv. No. 337-TA-550) (RX-76C:1-20).
- 22. VIVACS 1200405 (aka Vivacs 2) from the ITC case (Inv. No. 337-TA-550) (RX-75C:1-45).
- 23. VIVACS 0100506 (aka Vivacs 3) from the ITC case (Inv. No. 337-TA-550) (RX-74C:1-81).
- 24. Scientific Report: Attenuation Profile Comparison of Various MVA-Strains w/Well plates (aka Drillien Study) [Tab D & D2] from the ITC case (Inv. No. 337-TA-550) (RX-289C:1-80).
- 25. Scientific Report: Attenuation Profile Comparison of Various MVA-Strains from the ITC case (Inv. No. 337-TA-550) (RX-288C:1-14).
- 26. University of Zurich Study Report: Attenuation profile comparison of various MVA-strains, dated March 2006 from the ITC case (Inv. No. 337-TA-550) (RX-25C:1-25).
- 27. Nucleotide Alignment MVA-Antoine vs. Acambis 3000 MVA vs. MVA-BN (CX-66C:1-431) from the ITC case (Inv. No. 337-TA-550).
- 28. 3/31/06 Baxter BioScience Report GAEX166 from the ITC case (Inv. No. 337-TA-550)(RX-254C:1-4).
- 29. 4/11/06 Baxter BioScience Report GAEX168 from the ITC case (Inv. No. 337-TA-550)(RX-255C:1-6).
- 30. Corrigendum to Antoine et al. Virology (1998) from the ITC case (Inv. No. 337-TA-550)(RX-256-.1-2).

- 31. The Initial Determination in the ITC case dated September 7, 2006 (Inv. No. 337-TA-550).
- 32. Complainant's Petition for Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).
- 33. Respondent's Petition for Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).
- 34. OUII's Petition for Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).
- 35. Complainant's Response To Respondent's Petition For Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).
- 36. Complainant's Response To OUII's Petition For Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).

### **CURRICULUM VITAE: ROBERT DRILLIEN**

Born October 4, 1946 in Milan, Italy

Citizen: France

Work address: Institut de Génétique et de Biologie Moléculaire et Cellulaire 1 rue Laurent Fries,

67404 Illkirch, France

Téléphone: (33) 3 90 24 47 95

e-mail: robert.drillien@igbmc.u-strasbg.fr

Home address: 14 rue Waldteufel, Strasbourg, France

Telephone: (33) 3 90 41 48 73

### Diplomas:

High School Diploma, 1964, New York, New York Baccalauréat, 1966, Strasbourg, France Bachelor of Science in Biochemistry (Biochemistry), 1970, University of Strasbourg, France Masters in Biochemistry, 1972, University of Strasbourg, France PhD in Virology 1981, University of Strasbourg, France

### Training:

1970-1972:	Research training in the Genetics Laboratory (Professor François Lacroute) of the					
	School of Science, University of Strasbourg					
1981-1982:	Postdoctoral training in the Department of Virology, St. Mary's Hospital Medical					
	School, London, Great Britain (Professor Keith Dumbell)					
Positions:						
1972-1976:	Junior research associate in the Virology laboratory (Professeur André Kirn) of					
	the School of Medicine of the University of Strasbourg, France					
1976-1981:	Research associate at the French National Institute of Health and Medical					
	Research (INSERM): Laboratory of Pathogenesis of Viral Infections (Strasbourg,					
	France) directed by Professor André Kirn					
1981-1982:						
	School, London, Great Britain (Professor Keith Dumbell)					
1982-1986:	Research associate at INSERM, Pathogenesis of Viral Infections directed by					
	Professor André Kim					
1986-1988:	Temporary research position at Transgène (Strasbourg, France)					
1988-1992:	Research associate at INSERM, Pathogenesis of Viral Infections directed by					
	Professor André Kirn					
1993-1996:	Senior investigator at INSERM, Pathogenesis of Viral Infections directed by					
	Professor André Kirn					
1996-2004:	Senior investigator at the INSERM laboratory EPI 99-08 (Director: Daniel					
	Hanau) in the Etablissement Français du Sang (Blood Transfusion Center,					
	Strasbourg)					
2004-present:	Senior investigator at the INSERM laboratory of the IGBMC (INSERM U596),					
==- F	(III)					

### Illkirch, France (Director: Jean-Louis Mandel)

### Membership, committees and consultancies:

1996-present: French Gene Technology Committee (Commission de Génie Génétique). 1999-present: World Health Organization Advisory Committee on Variola Virus Research.

1996-present: American Society for Microbiology.

1996-present: British Society for General Microbiology.

2000-present: Advisor to the French Agency for the Security of Health Products (AFSSPS) on

Poxviruses.

2002-present: Advisor to European Pharmacopoeia on Poxviruses.

1988-present: Consultant to Transgene (Strasbourg, France) generally on Poxviruses.

2002-November 2005: Consultant to Bavarian Nordic (Kvistgård, Denmark) generally on

Poxviruses, unrelated to the technology of U.S. Patents No. 6,761,893 and No. 6,913,752.

### Recent Publications (2000-2005)

Hsiao, J-C, Che-Sheng Chung, C-S, Drillien, R, Chang, W. The cowpox virus host range gene, CP77, affects phosphorylation of eIF2□ and vaccinia viral translation in apoptotic HeLa cells. Virology, 2004, 329, 199-212.

Drillien R, Spehner D, Hanau, D. Modified Vaccinia Virus Ankara induces moderate activation of human dendritic cells. J. Gen Virol. 2004, 85, 2167-2175.

Spehner D, De Carlo S, Drillien R, Weiland F, Mildner K, Hanau D, Rziha H.-J. The appearance of the bona fide spiral tubule of Orf virus is dependent on an intact viral 10 kDa Protein, J. Virol. 2004, 78, 8085-8093.

Drillien, R., Spehner, D., Garin, D. Les virus candidats à un vaccin antivariolique de troisième génération. Méd. et Mal. Inf. 2004, S51-S54.

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Virology. 2000 Mar 15;268(2):471-81.

# **EXHIBITS 10-12** REDACTED IN THEIR **ENTIRETY**

## **EXHIBIT 13**

#### UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

Before the Honorable Robert L. Barton, Jr.

Administrative Law Judge

In the Matter of

Investigation No. 337-TA-550

Certain Modified Vaccinia Ankara

("MVA") Viruses and Vaccines and

Pharmaceutical Compositions Based

Thereon

### DECLARATION OF PROF. DR. DR. H.C. MULT, ANTON MAYR

### ERKLÄRUNG DES PROF. DR. DR. H.C. MULT. ANTON MAYR

- state:
- 1, Professor Anton Mayr, hereby declare and 1ch, Professor Anton Mayr, gebe hiermit folgende Erklärung ab:
- 1. I reside in Stamberg, Germany, and diseases such as small pox.
- 1. Ich bin wohnhaft in Starnberg, have spent nearly fifty years of my life Deutschland, und habe ungefähr 50 Jahre developing and researching a virus known as meines Lebens mit der Entwicklung und Modified Vaccinia Ankara (MVA), which has Erforschung eines Virus namens Modified therapeutic uses, including in vaccines against Vaccinia Ankara (MVA) verbracht, das therapeutischen Zwecken dient, einschließlich des Gebrauchs von Impfstoffen gegen Krankheiten wie zum Beispiel Pocken.

- 2. I have a doctorate degree and a honorary doctoral degrees from the University Universität Veterinary College of Hanover.
- 2. Ich habe einen Doktor- und einen professorship in veterinary medicine from the Professorentitel in Veterinarmedizin inne und University of Munich, and received various habe eine Reihe von Ehrendoktorgraden der Zürich, der of Zurich, Technical University of Munich and Universität München und der Tierärztlichen Hochschule in Hannover verliehen bekommen.
- 3. From 1955 to 1959, I was the director of the Department for Infectious and Tropical des Medicine and the Bavarian Vaccine Institut, Tropenkrankheiten Munich. From 1959 to 1963, I was the Landesimpfanstalt München. Von 1959 bis president of the Federal Research Institute for 1963 Virus Diseases in Animals, Tübingen, Bundesforschungsanstalt für Viruskrankheiten director of the Institute for Medical bis 1990 war ich Direktor des Institutes für Microbiology, Infectious and Epidemic Medizinische Mikrobiologie, Infektions- und Diseases, Veterinary Faculty, University of Seuchenmedizin der Tierärztlichen Fakultät der Munich. Since October 1991, I have been a Universität München. Seit 1990 bin ich researcher emeritus at the University of emeritierter Forscher an der Universität Munich.
- 3. Ich war von 1955 bis 1959 Mitarbeiter Institutes für Seuchen und und der Bayrischen war ich Präsident Germany. From 1963 to 1991, I was the der Tiere in Tübingen, Deutschland. Von 1963 München (Institut für Medizinische Mikrobiologie, Infektionsund Seuchenmedizin).
  - 4. I created MVA and all MVA strains
- 4. Ich habe MVA entwickelt und alle

MVA.

5. Until I gave an exclusive license and

institutes where I have worked.

originate from me. I created MVA, and a MVA-Stämme stammen von mir ab. Ich habe strain referred to as MVA-572, created by MVA geschaffen sowie einen weiteren continuous passages of a Vaccinia Virus in attenuierten Stamm mit der Bezeichnung chicken embryo fibroblasts. I am widely MVA-572, geschaffen durch kontinuierliche recognized and credited as the originator of Passagen eines Vaccinia-Virus Ankara in Fibroblasten von Hühner-Embryos (CEF). Ich bin weithin anerkannt und angesehen als der Schöpfer von MVA.

5. Bis zum Zeitpunkt, in dem ich ownership rights in MVA, including MVA-572 exklusive Lizenz- und die Eigentumsrechte an and its progeny, to a company named Bavarian MVA, einschließlich MVA-572 und dessen Nordic, I owned all MVA strains, including Nachkommenschaft, auf eine Gesellschaft MVA-572 and others that are presently on namens Bavarian Nordic im Jahre 2002 deposit, for example, at the European übertrug, gehörten mir alle MVA Passagen, Collection of Cell Cultures (ECACC). Prior to einschließlich MVA-572 und andere, die the transfer to Bavarian Nordic, which gegenwärtig zum Beispiel bei der European occurred over the period from 1996 to 2002, I Collection of Cell Cultures (ECACC) owned the MVA strains as the product of my hinterlegt sind. Vor der Übertragung an research as director and president of the Bavarian Nordic, die über die Jahre 1996 bis 2002 erfolgte, gehörten mir die MVA Passagen als das Produkt meiner Forschung als Direktor und Präsident der Institute, an denen ich gearbeitet habe.

- 6. I have provided some samples of MVA to individual scientists, upon request, for individuellen research purposes, but not for commercial Anforderung allein für Forschungszwecke zur purposes, such as to develop a vaccine product. Verfügung
- 6. Ich habe einige Stämme des MVA Wissenschaftlem auf gestellt, nicht iedoch kommerzielle Zwecke wie die Entwicklung eines Impfstoffes.
- 7. Upon request, I provided two samples me.
- 7. Auf Anforderung habe ich zwei Muster of MVA to Dr. Bernard Moss of the National des MVA Dr. Bernard Moss des National Institutes of Health (NIH). Specifically, Dr. Institutes of Health (NIH) gegeben. Genauer Bernard Moss of the NIH approached me in gesagt hat mich Dr. Bernard Moss vom NIH 1995 for a sample MVA virus and again in im Jahre 1995 um ein Muster des MVA Virus 2001. I provided Dr. Moss with a sample of gebeten und noch einmal im Jahre 2001. Ich MVA-575 in 1995 and with MVA-572 in habe Dr. Moss ein Muster des MVA- 575 im 2001. As is customary among researchers, I Jahre 1995 und des MVA-572 im Jahre 2001 provided Dr. Moss with samples for his verschafft. Wie es unter Forschern üblich ist, research purposes only, not for any commercial überließ ich Dr. Moss diese Muster nur für purpose, such as using it to create vaccine Forschungszwecke, nicht für kommerzielle product, or for any third party use. Dr. Moss Zwecke, wie die Nutzung zur Schaffung eines was not allowed to commercialize MVA. Dr. Impfstoffes oder für irgendeine Nutzung durch Moss was not permitted to give out any Dritte. Dr. Moss hatte keine Erlaubnis zur samples of MVA-572 or its progeny to any kommerziellen Nutzung des MVA. Dr. Moss third party without express permission from war nicht gestattet, Muster von MVA-572 oder seiner Nachkommenschaft an einen Dritten

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### CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER

ohne: mein**e** ausdrückliche Zustimmung herauszugeben.

- 8. A company called Therion approached Dr. Moss to receive a sample of MVA-572 wandte sich um den Februar 2002 an Dr. Moss, around February of 2002. Therion Biologics um ein Muster des MVA-572 zu erhalten. of Cambridge, Massachusetts wrote a letter to Therion me indicating that Dr. Moss would not provide Massachusetts schrieb einen Brief an mich mit MVA-572 to Therion without permission from dem Inhalt, dass Dr. Moss kein MVA-572 an me.
- 8. Eine Gesellschaft namens Therion Biologics Cambridge, Therion ohne Erlaubnis durch mich weitergeben würde.
- 9. At some point after September 11. 2001, Dr. Moss decided no longer to honor his September 2001 entschied sich Dr. Moss, die agreement with respect to MVA samples Vereinbarung hinsichtlich der MVA Muster, provided by me and decided to take my MVA die er von mir bekommen hatte, nicht mehr sample and use it as the basis for a commercial, einzuhalten, nahm meine MVA Muster und small pox vaccine product. I sent letters to Dr. nutzte sie Moss advising against such use of the MVA kommerziellen Pocken-Impfstoff. Ich schrieb sample. I believe that Bavarian Nordic, the Dr. Moss Briefe, in denen ich ihm von einem present owner, also sent letters and attempted solchen Gebrauch der MVA Muster abriet. Ich stop Dr. Moss and the NIH from glaube, unauthorized commercial use of the MVA-572 gegenwärtige Eigentümerin, ebenfalls Briefe or its progeny. MVA-572 and its progeny are geschrieben hat und versucht hat, Dr. Moss owned by Bavarian Nordic and no commercial und
  - 9. Zu einem Zeitpunkt nach dem 11. als Grundlage für einen dass Bavarian Nordic, das NIH von der unbefugten

use of this strain is permitted by any other kommerziellen Nutzung des MVA-572 und party without their permission.

seiner Nachkommenschaft abzuhalten. MVA-572 und seine Nachkommenschaft gehören Bavarian Nordic und ein kommerzieller Gebrauch dieses Stamms durch eine andere Partei ohne Erlaubnis von Bavarian Nordic ist nicht gestattet.

I declare upon penalty of perjury under the Ich erkläre unter Eides Statt nach den Gesetzen laws of the United States that the foregoing is der Vereinigten Staaten, dass die vorstehende true and correct.

Executed this \_\_\_\_ day of November, 2005.

Erklärung der Wahrheit entspricht.

Ausgefertigt am 1/4 November 2005.

Respectfully Submitted,

Prof. Dr. Dr. h.c. mult. Agton Mayr

# EXHIBIT 14 **REDACTED IN ITS ENTIRETY**

DB02:6039286.1 064417.1001 

## **EXHIBIT 15**

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BAV			

Plaintiff,

٧.

ACAMBIS INC. and ACAMBIS PLC.

Defendants.

Civil Action No. 05-614 (SLR)

## PROF. DR. DRES. H.C. JOSEPH STRAUS

### I. INTRODUCTION

- 1. My name is Joseph Straus and I have been retained as a legal expert on German Law by Bavarian Nordic A/S ("BN") in connection with the above-referenced case in the United States District Court for the District of Delaware to study and provide opinion on certain issues relating to ownership to and/or intellectual property rights in certain Modified Vaccinia Virus Ankara ("MVA") strains and vaccines.
- 2. I understand that BN alleges conversion with respect to certain live biological material based on the use of BN's proprietary MVA-572 strain as the precursor for developing, producing and selling the MVA3000 vaccine product at issue in this investigation.

### II. QUALIFICATIONS

- 3. I am the Director of the Max Planck Institute for Intellectual Property,
  Competition and Tax Law in Munich, and Professor of Law at the Universities of Munich and
  Ljubljana, in Germany and Slovenia respectively. I earned a Law Diploma in 1962 from the
  University of Ljubljana, Slovenia, and a Dr. jur. from Ludwig-Maximilians-Universität, in
  Munich in 1968. I worked in private practice from 1968 to 1977. Since then, I have worked at
  the Max Planck Institute. I have taught European and German Patent Law at LudwigMaximilians-Universität, Munich since 1990. Beginning in 1989 I have been a Visiting Professor
  of Law at Cornell Law School, Ithaca, N.Y., teaching accelerated courses on International
  Protection of Intellectual Property Rights. I was also a Visiting Professor at the George
  Washington University Law School in 2001 and 2002, and am the Marshall B. Coyne Visiting
  Professor of International and Comparative Law at the same institution, regularly teaching
  courses on biotech and chemical patents. Moreover, I was a Distinguished Visiting Professor at
  the Faculty of Law, University of Toronto in Spring 2005.
- 4. I am a former President of the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP); Vice President of the German Association for the Protection of Industrial Property and Copyright Law (GRUR); Chair of the Program Committee of the International Association for the Protection of Intellectual Property (AIPPI); Chair of the Intellectual Property Rights Committee of the Human Genome Organisation (HUGO); 1999 Katz-Kiley Fellow of the University of Houston Law Center; and an Arbitrator with the International Court of Arbitration of the International Chamber of Commerce, Paris. I have served as a consultant to OECD, WIPO, UNCTAD, UNIDO, ECCOmmission, World Bank, Scientific Services of the German Bundestag, the European Patent

Organisation, the Swiss Federal Government and the Swiss Federal Institute of Intellectual Property. I have authored or co-authored numerous publications in the field of intellectual property law. I am a recipient of many awards and honorary degrees.

- 5. I am a member in the following advisory bodies and scientific organisations:

  Standing Advisory Committee before the European Patent Organisation (SACEPO); Advisory

  Board of the Worldwide Academy of the World Intellectual Property Organisation (WIPO);

  Standing Committee "Intellectual Property Rights" All European Academies (ALLEA);

  Executive Council of the Center for Advanced Study and Research on Intellectual Property

  (CASRIP) of the University of Washington, School of Law, Seattle; Advisory Council of the

  McCarthy Institute for Intellectual Property and Technology Law, University of San Francisco,

  School of Law, San Francisco and International Board of Assessors of the Intellectual Property

  Research Center, University of Melbourne; Corresponding Member of the Slovenian Academy

  of Science and Art; Member of the Academia Europaea; and Member and Dean of the Class for

  Social, Legal and Economic Sciences of the European Academy of Sciences and Arts. I actively

  research such areas as European and International Patent Law, International Protection of

  Intellectual Property Rights, Technology Transfer, and employee's inventions.
- 6. I have provided legal opinions in a great number of patent cases litigated for instance in Dutch, German, Italian, Japanese, Slovenian, Swiss and U.S. courts for companies such as Bayer, Dade-Behring, Boehringer Ingelheim, Glaxo-Wellcome, Merck, Novartis, Pfizer, Roche, SmithKline Beechem, Texas Instruments, 3M and others. Upon request of the German and Austrian Government I testified before competent committees of the respective Parliaments, and at the request of the European Commission, before the Committee on Legal Affairs and Citizen Rights of the European Parliament, on various issues of patent law, especially on biotech

patents.

- 7. I am being compensated in this matter at my usual hourly rate, in addition to reimbursement for out-of-pocket expenses. My right to compensation is in no way contingent upon the outcome of the case or any issue in it. I have never testified as an expert and have not been deposed for trial. Further, I have not been retained as or testified as an expert on this subject matter in any other litigation.
- 8. In forming the opinions expressed below, I have reviewed and relied at least on certain documents listed in Exhibit A and my legal expertise in German law (cf. e.g. Straus/Moufang, Deposit and Release of Biological Material for the Purposes of Patent Procedure, Baden Baden 1990).

### III. EXPECTED TESTIMONY AND OPINIONS

- 9. BN's proprietary rights relate to the MVA vaccine stock and MVA viral stock developed by and/or in the possession of Prof. Mayr, including without limitation property rights, intellectual property rights, and damage and royalty claims for uses of MVA and know how pertaining thereto, and comprises claims for compensation against third parties accruing pre and post transfer of these rights to Bavarian Nordic in 2002.
- 10. I am prepared to testify that under German law no transfer of rights occurred between Prof. Mayr and Dr. Moss and/or NIH with respect to MVA-572 and/or its progeny, either as a direct transfer or based on good faith receipt.
- 11. I am prepared to testify that under German law no transfer of ownership rights, or commercial rights, took place between Prof. Mayr or BN to Dr. Moss and/or NIH with respect to MVA-572 and/or its progeny, as a direct transfer or based on bona fide purchase.

12. I am also prepared to testify that under German law no transfer of ownership rights, or commercial rights, took place between Prof. Mayr or BN and/or Dr. Moss and/or NIH to Acambis with respect to MVA-572 and/or its progeny, as a direct transfer or based on bona fide purchase.

## IV. MY OPINION REGARDING OWNERSHIP OF BIOLOGICAL MATERIAL

- 13. This case concerns a man-made virus known as Modified Vaccinia Ankara ("MVA"), which is a member of the genera Orthopoxvirus in the family of Poxviridae. The MVA virus was created by the German Prof. Anton Mayr in Germany through a process of 516 serial passages of the Chorioallantoic Vaccina Ankara (CVA) strain on chicken embryo fibroblasts (CEF) cells (see Mayr, A., Hochstein-Mintzel, V. and Stickl, H. [1975] Infection 3, 6-14). As a consequence of these long term passages, the resulting MVA virus deleted about 31 kilobases of its genomic sequence and, therefore was described as highly host cell restricted to avian cells (Meyer, H. et al., J.Gen. Virol. 72, 1031-1038[1991]). It was shown in a variety of animal models that the resulting MVA was significantly avirulent (Mayr, A. & Danner, K. [1978] Dev. Biol. Stand. 41: 225-34).
- 14. Prof. Mayr developed the MVA virus from CVA over a time period of several years. First while being the Director of the Department of Microbiology at the Federal Research Institution for Virus Diseases in Animals, Tübingen, Germany between 1955-1959, and then as the President of the same institute in 1959-1963. Prof. Mayr continued this work towards creating the MVA virus as the Director of the Institute for Medical Microbiology, Infectious and Epidemic Diseases, Veterinary Faculty, University of Munich, Germany, 1963-1991. In the

early 1970-ies, Prof. Mayr reached the 516th passage and renamed the virus into MVA.

Before addressing the ownership of Professor Mayr in the virus MVA, it should 15. be clarified that under the applicable German law it is irrelevant for the issue of property rights whether the physical object is animate or inanimate. Consequently, there can be no doubt that micro-organism cultures are "tangible goods" from the point of view of property law. Ownership in such tangible goods can be acquired by assignment by means of a legal transaction, acquisition of an ownerless tangible good, treasure trove, manufacture of new tangible goods, combining, and mixing (commingling). The proprietor of a tangible good automatically acquires title to its products (and other component parts) as a matter or principle. Thus the property right covers also those micro-organisms that were removed from the original culture and have been reproduced further. This right is not restricted just to leaving products, however, but also applies, for example, to extracted metabolic products of micro-organisms and monoclonal antibodies produced from hybridoma cell lines. For the definition of the term "product", it is irrelevant whether the production process is caused by nature alone or is based on the result of human labor. Title could at most be lost if the owner of the biological material were to produce a new tangible good by processing or converting it. Under German tangible property law, however, this would presuppose that a result were achieved which displayed new properties as compared to the starting material and which constituted a new and independent asset. Whether a third party who uses biological material that is not his property to produce valuable substances "manufactures new tangible goods" and thus acquires title to the substances depends on the concrete facts of the individual case. The position resulting from the title to the biological material does not only provide the proprietor with remedies against unauthorized possessors. Rather, he can also utilize it by reserving title within the framework of licensing agreements (cf. Straus/Moufang, op. cit.,

pp. 96-100 with numerous further references).

- Under the German laws applicable to the facts of this case, a consequence of 16. Article 5 III of the German Constitution (Grundgesetz - GG), in which the freedom of research is guaranteed and which, in the context of the issue at hand, also covers the right of exploitation and the respective exploitation activities, guaranteed under Articles 2, 12, 14 at Seq. GG (Frieling, Forschungstransfer: Wem gehören Forschungsergebnisse [Research Transfer: To Whom Belong Research Results], 1987 GRUR 407 at Seq., at 408), was that tangible as well as intangible results of the research work of a university professor belonged to the professor (Frieling 1987 GRUR 408 at seq.). It was up to the professor to take the decision whether and in which form to exploit own research results (Ullrich, Privatrechtsfragen der Forschungsförderung in der Bundesrepublik Deutschland [Civil Law Issues of Research Promotion in the Federal Republic of Germany], 1984, p. 290). In respect to inventions made by German university professors before February 7, 2002, the German Law on Employees Inventions in its Section 42 explicitly provided that "inventions made by professors, lecturers and scientific assistants, in their capacity as such, at universities and higher schools of science shall be free inventions." Since the facts at hand in this case all occurred before February 2, 2002, no need exists to examine the impact of the new law, neither in the context of tangible nor intellectual property.
- 17. It is undisputed under the German law that tangible scientific research results, including naturally occurring substances such as bacteria or viruses, at least if they are limited in space, either by their own physical delimitations, or by being placed in a container or by some other artificial means, can be subject matter of tangible property rights (*Straus/Moufang*, op. cit., p. 96 and footnote 265 with further references). It is further undisputed that where the scientific and economic value of a research result is inseparably attached to the originally discovered or

arranged tangible object, either because its reproduction is not possible, too expensive or too complicate, and especially if it can be achieved only by the reproduction of the object, i.e. of the micro-organisms itself, the exploitation interest of the researcher is expressed in his discretionary control over the object (*Frieling*, 1987 GRUR 410).

- 18. As indicated above (No. 15) tangible property in biological material can be acquired by means of a legal transaction, acquisition of an ownerless tangible good, treasure trove, manufacture of a new tangible good, combining, and mixing (commingling). Isolating or genetically altering a micro-organism is viewed as being tantamount to manufacturing a new tangible good, to which the researcher acquires title under Section 950 BGB (German Civil Code), provided the entire economic value of the exploitation potential of the further processed tangible research result is not much less than that of the starting material (*Frieling*, 1987 GRUR 410, 411, who uses as an example in vitro bred viral lines [Virenstämme] as compared with single viruses. Thanks to adding and mixing single viruses with nutrient substrates, viruses acquire the ability of continuous reproduction).
- 19. Since a university professor, due to his status guaranteed independence (Section 43 of the Law on Higher Eduction [Hochschulrahmengesetz HRG]) cannot be directed to a specific result of his work by the employer, his right to individually take initiative for research activities always prevails, with the consequence that he has the right to dispose over tangible results of his research work. This is true even if the raw materials used for manufacture were put at his disposal by the University. In this context the property right in the raw material is viewed to be vanished (*Frieling*, 1987 GRUR 412: "Daran ändert sich ohne weiteres nichts, wenn die Materialien für die Herstellung von der Hochschule bereitgestellt wurden. Das Eigentum an den Rohstoffen geht regelmäßig gemäß § 950 II BGB unter").